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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 10, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-40

Allen L. Clark
President and Chief Executive Officer
Performance Modalities, Inc.
25510 74th Avenue South
Kent, Washington 98032

WARNING LETTER

Dear Mr. Clark:

A Food and Drug Administration (FDA) inspection was conducted of your medical gas facility located at Performance Home Medical, 25428 74th Avenue South, Kent, Washington, on March 19, 20, and 22, 2002. Medical gases are drug products as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for medical gases, Title 21, Code of Federal Regulations (21 CFR), Part 211. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, storage, or holding, are not in compliance with CGMP regulations.

The deviations include the following:

1. Failure to test incoming bulk liquid Oxygen U.S.P. for identity and strength, or to assure the identity and strength of your incoming bulk liquid Oxygen U.S.P., prior to filling liquid cryogenic home units [21 CFR 211.165(a)]. Your firm was unable to produce Certificates of Analyses for bulk liquid Oxygen U.S.P., received [redacted] between December 19, 2001, and March 18, 2002.

2. Failure to establish adequate batch production records for each batch of drug product produced to document each significant step in the manufacture, processing, packing, and holding of each batch of drug product was accomplished [21 CFR 211.188(b)]. No batch production records were maintained for liquid Oxygen U.S.P. transfilled into home units on December 19, 2001, January 18, 2002, January 25, 2002, and February 5, 2002.

3. Failure to properly calibrate the [redacted] Oxygen Analyzer used to test the identity of bulk liquid Oxygen U.S.P. in that a certified calibration standard of Oxygen U.S.P. is not utilized to calibrate the instrument; and there is no established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met [21 CFR 211.160(b)(4)].

4. Failure to maintain records documenting the periodic calibration of the [redacted] Oxygen Analyzer [21 CFR 211.194(d)].

5. Failure to establish written procedures designed to assure that drug products have the identity and strength they purport or are represented to possess [21 CFR 211.100(a)] in that the "Oxygen Procedures" do not include detailed instructions on performing identity testing, including, but not limited to, how to perform the test, what the expected results should be, how the results will be documented, and what action will be taken in the event the results are out of range.

6. Failure to perform adequate prefill operations, through testing and examination of each cryogenic home unit, prior to filling [21 CFR 211.84(a)].

7. Failure to establish written procedures for the receipt, identification, storage, handling, sampling, and examination of all Oxygen U.S.P. labels [21 CFR 211.122].

8. Failure to establish a quality control unit having the responsibility and authority to review production records to assure that no errors have occurred, and if errors have occurred, that they have been fully investigated [21 CFR 211.22(a)].

9. Failure to establish written procedures for the receiving of any complaints [21 CFR 211.198)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. Possible actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Seattle District Office, 22201 23rd Drive SE, Bothell, Washington, 98021-4421, to the attention of Lisa M. Althar, Compliance Officer. Should you have any questions concerning this letter, Ms. Althar can be contacted by telephone at (425) 483-4940.

Sincerely,

Charles M. Breen
District Director

Enclosure:
FDA 483

cc: Steven A. Surprenant
Branch Manager
Performance Home Medical
25428 74th Avenue South
Kent, Washington 98032